

### **REMARKS**

This is in response to the Office Action dated January 5, 2010.

Per the above amendment, claims 1, 4, 10-11 and 17-18 have been amended.

Claims 1, 5, 6, 10, 11 and 17 stand rejected under 35 USC 102(b) as being anticipated by Stevens (US 3,073,307).

Stevens discloses a needle hub assembly 10 that is made up of a hub body section 11 joined to a sheath portion 21 by a weakened section. The needle cannula 12 is embedded into the needle hub assembly by means of a ferrule or eyelet retaining ring section 13 (column 3, lines 42-53). The Stevens device therefore is a needle hub assembly adapted to be "fixedly mounted on the discharge outlet of a hypodermic syringe" that has severable but integral needle sheath section that sealingly encloses the needle cannula extending from the needle hub (column 2, lines 54-63). A plurality of projections 26 extend radially outwardly along substantially the entire length of sheath 21.

The instant invention, aside from being a one-piece cylindrical body having a neck with an aperture dimensioned to accept a needle hub, further has finger grasp means coupled to the cover at a desired location along the length of the cover. By providing the finger grasp means at the desired location, the predetermined torque applied by the user at the finger grasp means would amplify the torque so that the cover is readily separated from the neck at the weakened joint. In contrast to the projections 26 at sheath 24 that extend substantially along the entire length of the sheath in the Stevens device, the finger grasp means for the instant invention is provided only at a desired location along the length of the cover. Such configuration is also set forth in claims 11 and 18. By that limitation alone, it is clear that each of independent claims 1, 11 and 18 is not anticipated by Stevens. It should moreover be noted that there are additional myriad limitations set forth in claims 11 and 18 that render Stevens not an anticipation, or obvious, reference.

There is nothing in Stevens that discloses the first and second portions of the lock mechanism as defined in claim 5, or the needle hub assembly as set forth in claim 6. Furthermore, it is hard-pressed to consider the projection 26 as a wing, per set forth in claim 10, particularly when the wing is integrated at the desired location along the length of the cover.<sup>1</sup>

Claims 7, 8 and 16 stand rejected under 35 USC 103(a) as being obvious over Stevens. The examiner asserts that the recited torque is obvious.

It submitted that the examiner's reasoning is without merit for the predetermined torque was found to be a torque that would not have force sufficient to separate the cover from the body, as the "weakened joint" has been designed to withstand the recited torque. In other words, were the Stevens weakened joint to have been designed to withstand the recited torque force, sheath 24 would not be broken away from body 10 unless a force greater than 60 ounce inches were to be applied. Thus, the fact that a smaller torque force may be used for breaking the cover from the rest of the body, by using the finger grasp means, is non-obvious over the cited prior art.

Claims 2-3, 14 and 20 stand rejected under 35 USC 103 (a) as being obvious over the combination of Stevens and Netherton et al. (US 4,900,309). The examiner asserts that the Netherton device is a wingnut.

In contrast to the assertion by the examiner, Netherton actually discloses a needle shield that happens to have a number of ribs 40 at its peripheral rim 36, and are meant to facilitate the gripping of shield 10 for insertion over needle cover 18. Moreover, ribs 40 are meant to prevent rolling of shield 10 (see column 3, line 63 to column 4, line 4). Shield 10

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<sup>1</sup> It is assumed that independent claim 18 stands rejected under Stevens in the same anticipation rejection, as the examiner fails to note such in the office action.

therefore is not the wingnut as set forth in claims 2, 3, 14 and 20. Nor could it be said that ribs 40 are wings.

Claims 9 and 12-13 stand rejected under Stevens in combination with Newby et al. (US 6,436,086).

It is submitted that Stevens could not be combined with Newby insofar as Stevens is a needle assembly having a luer end (body section 11) that is not fittable to the device disclosed in Newby. This is apparent insofar as the Stevens device relates to a hypodermic needle hub, and it is well known in the medical art that a hypodermic needle is not the same as a double ended needle.

In view of the foregoing, applicants submit that the instant invention is patentable over the cited prior art.

Respectfully submitted,



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